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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,604	12/07/2001	Pablo D. Garcia	PP016466.0002	6543

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/016,604	GARCIA ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,10 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,10 and 13-15* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed 26 December 2006. Claims 2, 8, 9, 11, 12, and 16-38 have been canceled. Claims 1, 3-7, 10, and 13-15 are pending and under final rejection.

Claims 1 is objected to because of the following informalities: the recitation of "gag or pol" should be changed to "Gag or Pol" to be in accordance with the art-recognized nomenclature of protein names. Appropriate correction is required.

Claims 4-7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claims 4-7 recite "wherein the expression products is an RNA comprising SEQ ID NO:155 and SEQ ID NO: 5," which does not further limit the base claim recitation "wherein said expression product is an RNA corresponding to the Gag or Pol domain of said retrovirus.

Response to Arguments

Claim Rejections - 35 U.S.C. §112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1, 3-7, 10, and 13-15 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement is **maintained.**

Examiner's rejection in the Action mailed on 23 August 2006 is as follows:

Applicants have not met the requirement for the written description in terms of the following factors: partial structure, physical and/or chemical properties, and functional characteristics alone or coupled with a known or disclosed correlation between structure and function.

Applicants have not disclosed the conserved structure in the identical regions or have compared structures between the 16 gene products and all of the HML-2 retroviral genes as claimed. In addition, as indicated in the previous Office Action, one species of the claimed genus of HML-2, HERV-K 22q11, has a negative effect wherein higher EST expression is found in normal prostate tissue than in a cancerous prostate sample, so this gene product would not detect prostate cancer in the claimed method. Even Applicants themselves admit that the one skilled in the art has to "determine which HML-2 retrovirus-encoded expression products are up-regulated in patients having prostate cancer, and which are not" on tope of page 9 of the response filed on 21 July 2006. Therefore, Applicants are clearly not in possession of the entire broad genus of products to practice the claimed method. Likewise, Applicants are not in possession of the HML-2 retroviral products that are indicative of prostate cancer in a blood sample because the specification nowhere describes the partial or conserved structure of a blood sample that correlates with the function of indicating prostate cancer.

In the response filed on 26 December 2006, Applicants argue that the specification describes 16 RNA expression products with the consensus sequences corresponding to the HML-2 Gag domain (SEQ ID NO:11), HML-2 5' Pol region (SEQ ID NO: 12) and the HML-2 3' Pol region.

Applicants' argument has been fully considered but is not persuasive. The specification describes expression products corresponding to portions of the Gag and Pol domain of HML-2 retroviruses with the specific sequences of SEQ ID NO: 11, 12 and 13. Therefore, Applicants are only in possession of the screening method comprising assaying the RNA level of HML-2 expression product comprising SEQ ID NO: 11, 12 or

13, but not in possession of the screening method comprising assaying the RNA expression level of *any portion or the entire region* of HML-2 Gag or Pol domain.

The rejection of claims 1, 3-7, 10 and 13-15 under 35 U.S.C. § 112, first paragraph, as being lack of enablement is **maintained**.

Examiner's rejection in the Action mailed on 23 August 2006 is as follows:

Applicants leaped to the conclusion that an increased level of a HML-2 expression is correlated with the diagnosis of prostate cancer. The claimed method of prostate cancer diagnosis by detecting HML-2 expression product is highly unpredictable without studies of how the up-regulation of HML-2 is widely distributed among prostate tumors in both tissue and blood samples. Even though the claimed method of diagnosis is defined as to exclude distinguishing between prostate cancer and other types of cancer, there is still the uncertainty of whether HML-2 gene expression is indeed elevated in every prostate tumor sample. Aside from the lack of correlation, there is no guidance to determine whether the at least 150% increased level of HML-2 retroviral product in a blood sample is exclusively associated with prostate cancer and no other cancer. The specification does not provide guidance on the operative versus the inoperative HML-2 retroviral species. One skilled in the art is burdened with the undue experimentation of identifying every operative HML-2 retroviral expression products that correlate with prostate cancer in the prostate tissue and in the blood before the claimed method can be used.

In the response filed on 26 December 2006, Applicants argue that the claimed method, as amended, does not require a definitive diagnosis of cancer because claim 1 recites a method of screening for prostate cancer.

Applicants' argument has been fully considered but is not persuasive. The specification is not enabling for the claimed method of screening for prostate cancer as the 16 PCR clones described on page 77 and in Table 6 are not all correlated with prostate cancer. Changing the limitation from "diagnosing" to "screening" does not overcome the rejection. The new limitation in the amended claims, "screening for

prostate cancer" is not supported by the specification because not all 16 clones detect at least 150% elevated expression of mRNA in 13 patients. Apparently not all the HML-2 retroviral expression products can be used to screen for prostate cancer. Furthermore, 13 patients cannot represent the whole population of prostate cancer patients. Finally, the working example does not support the limitations in the claimed method. In conclusion, Applicants have not provided objective evidence to address the uncertainty of whether HML-2 gene expression is indeed elevated in every prostate tumor sample.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey Parkin, Ph.D.
Primary Examiner
16 March 2007

Louise Humphrey, Ph.D.
Assistant Examiner